ACG Clinical Guideline on Crohn's Disease: A Point of View from Europe

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Running Head: Crohn's Disease Management

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To the Editor: I have read with great interest the new edition of ACG guidelines on Crohn disease (CD) (1). Most of the statements are immediately applicable not only in the United States, but also in Europe.

There are however some small but important differences in the management of these patients in Europe.

Regarding the diagnostic methods, the authors focused mainly on Computed tomography enterography (CTE) and magnetic resonance enterography (MRE). In Europe bowel ultrasonography is a widely used diagnostic method that has shown to have a comparable diagnostic accuracy, with a lower cost and no radiation emission (the latter feature compared to CTE) (2). If bowel ultrasonography is not widespread in the USA, it would be interesting to know why.

Regarding the factors that can influence the course of the disease, the authors concluded that there are no studies on CD concerning the use of selective cyclooxygenase-2 inhibitors (Coxibs) and that in a short-term therapy they have not shown to cause exacerbation of ulcerative colitis. An European meta-analysis found that gastrointestinal symptoms appear in most cases after a few days of use of Coxibs, and that the risk of worsening intestinal symptoms can occur mainly in patients with an active intestinal disease (3). Therefore, a possible strategy could be a careful follow-up of patients with inactive IBD during the first few days of treatment with Coxibs, due to a possible intestinal relapse, but in patients with a good tolerance in the first two weeks, a long- term therapy could be feasible (up to three months).

Finally, the authors have dedicated a paragraph to biosimilar anti-TNF agents. They have mentioned a randomized, non-inferiority phase 4 research on patients affected by CD, ulcerative colitis, spondyloarthritis, rheumatoid arthritis, psoriatic arthritis, and plaque psoriasis showing that switching from infliximab originator to CT-P13 (biosimilar) was not worsening the course of the disease more than continuing with

the originator (4). A letter from Europe commenting on the research emphasized that the results on CD itself are emblematic of the statistical problems associated with this study: among the 175 patients with CD, the risk of disease worsening was –14.3%, close to the 15% non-inferiority margin, and the risk would have exceeded 15% if the results of the most rigorous intention-to-treat statistical analysis had been reported instead of the per-protocol analysis (5). Furthermore, the authors (4) themselves pointed out that the study did not have sufficient statistical power to show non-inferiority in individual pathologies (i.e. CD). It would be interesting to know more comments on a hot topic like that of the efficacy of biosimilars.

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